



Attorney's Docket No.: 119381-00003 / 3704US

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Thomas Julius BORODY
Serial No. : 10/541,528
Filed : July 7, 2005

Art Unit : 1657
Examiner : Wood, Amanda P.
Confirm. No.: 1484

Title : **A CULTURE MEDIUM AND A METHOD FOR DETECTION OF PARASITES**

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Commissioner for Patents
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PETITION PURSUANT TO 37 C.F.R. §1.181 FOR RECONSIDERATION OF THE FINDING OF LACK OF UNITY AND WITHDRAWAL OF THE RESTRICTION REQUIREMENT

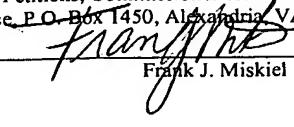
Dear Sir:

Applicant hereby submits a Petition pursuant to 37 C.F.R. §1.181 for reconsideration of the finding of lack of unity and withdrawal of the requirement for restriction made final in the Office Action, mailed April 15, 2008, in connection with the above-captioned application.

Remarks begin on page 2 of this paper.

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Frank J. Miskiel

REMARKS

The fee for filing the Petition and any other fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 02-1818. If a Petition for Extension of Time is needed, this paper is to be considered such Petition.

Applicant respectfully submits that there is a novel common underlying technical feature shared amongst all pending claims. Therefore, all pending claims (*i.e.*, Groups I-III) are unified and should be examined in this application.

Request for Waiver of the Two Month Requirement for Filing the Petition

Applicant recognizes that the filing of this Petition is not quite within the two month period recited in 37 CFR 1.181(f). Applicant respectfully requests consideration of this Petition in the interest of compact prosecution. As Applicant demonstrates below, the instant claims, when construed in light of the specification, are novel over the cited reference and share a common technical feature. Hence, the claims currently restricted to Groups I-III are unified and should be examined in one application. A decision on this Petition at this time would allow Applicant to avoid filing unnecessary divisional applications.

1. The Restriction Requirement

The Office Action, mailed September 20, 2007, restricted the pending claims into three groups as follows:

- I: Claims 1-11, drawn to a biphasic culture medium;
- II: Claims 13-17, drawn to a kit including the biphasic culture medium; and
- III: Claim 19-29 and 31-37, drawn to a method of detecting protozoa.

The Examiner, applying the rules of unity of invention under PCT Rule 13.1, alleged that a lack of unity exists because the three groups allegedly do not relate to a single inventive concept. This conclusion was based upon the premise that a special technical feature between the groups, a biphasic culture medium in which the liquid phase contains 3 specified ingredients and optionally an antibiotic, is disclosed in Clark *et al.* (Clin Microbiol Reviews 15: 329-341 (2002)).

2. Response to the Restriction Requirement

On March 20, 2008, Applicant responded to the Office Action, traversing the Requirement for Restriction. The claims were amended to incorporate limitations from dependent claims and to replace the recitation "including" with the recitation "consisting essentially of" to render it clear that the liquid phase of the biphasic medium contains three specified ingredients and one optional ingredient but excludes any additional unspecified ingredient(s) that would affect the basic and novel characteristics of the liquid phase.

Independent claim 1 of Group I is directed to:

*A bi-phasic culture medium, comprising:
a solid phase containing an egg slope or agar slope; and
a liquid phase consisting essentially of a serum, a peptone, a phosphate buffered saline and optionally an antibiotic.*

Claim 13 of Group II is directed to:

*A kit, comprising:
a container containing the medium of claim 1; and
a container containing rice starch.*

Claim 19 of Group III is directed to:

*A method of detecting the presence of protozoa in a specimen, the method including:
adding to the medium of claim 1, the specimen, rice starch and where necessary,
an antibiotic;
allowing the medium to incubate for a time period so as to cultivate protozoa; and
examining at least a portion of the incubated medium to detect the presence of
protozoa.*

Claim 20 of Group III is directed to:

*A method of detecting protozoa in faecal matter, comprising:
adding to the medium of claim 1 faecal matter, rice starch and where necessary,
an antibiotic;
allowing the medium to incubate for a time period so as to cultivate intestinal
protozoa; and
examining at least a portion of the incubated medium to detect the presence of
the protozoa.*

Disclosure of the Cited Art

Clark *et al.* describes diphasic LE medium and diphasic Robinson's medium (see pages 332-333). The diphasic LE medium includes Locke's solution (an aqueous solution of sodium chloride, calcium chloride, potassium chloride, magnesium chloride, monobasic and dibasic sodium phosphate, sodium bicarbonate and monobasic potassium phosphate) as a liquid phase overlaying an egg slant (page 332). The LE medium optionally contains 20% human or horse serum in the liquid phase (page 334). It thus includes more than the specified ingredients of the liquid phase as instantly claimed.

Clark *et al.* also describes diphasic Robinson's medium, which is a complex medium that includes twelve ingredients in the liquid phase. The preparation of Robinson's medium involves the preparation of six separate aqueous stock solutions: a). 0.5% erythromycin; b). 20% bactopeptone; c). potassium hydrogen phthalate and sodium hydroxide; d). "R medium," which contains sodium chloride, citric acid, potassium phosphate monobasic, ammonium sulfate, magnesium sulfate and lactic acid; e). "BR medium," which is "R medium" as described in (d) inoculated with a live standard *E. coli* strain; and f). "BRS medium," which is "BR medium" as described in (e) to which an equal volume of heat inactivated bovine serum is added (see page

333). Aliquots of solutions a), b), c) and f) are combined to form a liquid phase, which is layered over an agar slant yielding a biphasic medium.

The liquid phase as instantly claimed contains only three recited components and one optional component. In contrast, LE medium and Robinson's medium described in Clark *et al.* contain 8 and 12 recited components, respectively, in the liquid phase. Hence, the media as claimed are not disclosed in Clark *et al.* As noted above, the recited media are an element in every pending claim. Thus, all pending claims (*i.e.*, Groups I-III) share a novel common underlying technical feature. Therefore, all claims are unified and should be examined in this application.

3. The Office Action mailed April 15, 2008

In the Office Action, mailed April 15, 2008, the Examiner maintains the lack of unity rejection and makes the requirement for restriction final. The Examiner states that for examination purposes, "consisting essentially of" is equivalent to "comprising" so that the claims read on the media of Clark *et al.* Applicant respectfully petitions for reconsideration and withdrawal of the requirement for restriction.

RELEVANT LAW

The phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, *absent a clear indication in the specification or claims of what the basic and novel characteristics actually are*, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 [emphasis added].

Analysis

The phrase "consisting essentially of" can be construed as equivalent to "comprising" for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103 if there is no clear indication in the specification or claims of the basic and novel characteristics of the claimed subject matter. Applicant respectfully submits that, in this instance, the specification provides a clear indication of basic and novel characteristics of the claimed subject matter. The application provides a biphasic medium in which the liquid phase contains three recited components and optionally an antibiotic. The specification recites that the liquid phase of the biphasic medium has been simplified in comparison to media described in the art. For example, see page 4, lines 4-20, which recites:

In the present invention the culture method and medium has been simplified to a less complex medium but one that will in use, support the growth of the protozoa referred above including *D. fragilis*, *Blastocystis hominis* (*B. hominis*) and other parasites including other amoebae (for example *E. histolytica/dispar*, *Iodamoeba butschlii* *Endolimax nana*, *Entamoeba coli*, *Entamoeba hartmanni* being other pathogens). The medium in accordance with the invention can double as a transport medium where a sample is taken off-site from the laboratory and then transported to the laboratory. The culture medium preferably uses an egg slope as opposed to previous used saline agar cultures. The egg slope may be made by any appropriate method known in the art, for example by diluting hen's eggs 50/50 in either Ringer's salt solution or PBS (phosphate buffered saline). The culture medium of the invention demonstrates enhanced reliability of culture. The medium is not as complex as those described in the prior art which comprise numerous chemicals. The medium in accordance with the present invention is--by culture standards--greatly simplified yet more reliable. Unlike the use of live *E. coli* bacteria (which are not suitable to be given to patients in order to collect their own specimens), the medium in accordance with the invention is designed to work even more reliably without *E. coli*.

The specification describes the claimed liquid phase as less complex because it requires fewer ingredients, is easier to prepare and use, is more reliable, eliminates the need to include *E. coli*, has a long shelf life and is easily transportable. Hence, the specification provides a clear indication of novel characteristics of the claimed subject matter that distinguish it over the prior art. Accordingly, because the specification provides a clear indication of basic and novel characteristics of the claimed subject matter, and claims are read in light of the specification, the phrase "consisting essentially of" should be construed to mean that additional unspecified ingredients that would affect the basic and novel characteristics of the liquid phase are not included.

The media of Clark *et al.* contain ingredients that would affect the basic and novel characteristics of the liquid phase as instantly claimed. For example, the liquid phases of the media as instantly claimed include three recited components and optionally an antibiotic. The media described in Clark *et al.* contain 8 and 12 recited components, including calcium chloride, magnesium chloride, sodium bicarbonate and *E. coli*. The presence of calcium chloride and/or magnesium chloride and/or sodium bicarbonate can materially affect the basic and novel characteristics of the liquid phase because the presence of such salts increases the number of ingredients in the medium and also can eliminate the ease of preparation of the medium. For example, in order to prepare the liquid phases of its media, Clark *et al.* describes the preparation of numerous separate stock solutions and their subsequent combination to yield its liquid phases. Clark *et al.* also states that its combination of salts may precipitate after sterilization, necessitating additional filtration steps to remove any precipitate and further sterilization (see

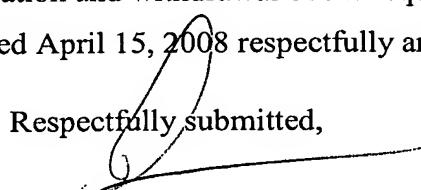
page 332). This precipitation of salts also can result in batch-to-batch variation of the liquid phase due to the variation in any precipitation and subsequent filtration. Thus, adding the salts of Clark *et al.* to the liquid phase of the medium as instantly claimed would affect the basic and novel characteristics of the instantly claimed liquid phase because it makes it more complex, more difficult to prepare and less reliable because of possible variation between batches. Further, the instant specification states that it is not suitable to give patients a medium that includes live *E. coli* in the liquid phase for collection of their own specimens. The media of Clark *et al.* include *E. coli* in the liquid phase. Hence, the liquid phase of the media described in Clark *et al.* includes ingredients that would affect basic and novel characteristics of the liquid phase as instantly claimed.

Applicant respectfully submits that the liquid phases in the instantly claimed media contain only three recited components and optionally an antibiotic. In contrast, the LE medium and Robinson's medium described in Clark *et al.* contain 8 and 12 recited components, respectively, in the liquid phase. As discussed above, the additional ingredients in the liquid phase of the media described in Clark *et al.* would affect basic and novel characteristics of the liquid phase as instantly claimed. Hence, the media as claimed are not disclosed in Clark *et al.* Thus, the media as claimed are novel over Clark *et al.* As noted above, the recited media are an element in every pending claim. Therefore, Clark *et al.* does not destroy unity and all pending claims (*i.e.*, Groups I-III) are unified and should be examined in this application. Applicant respectfully requests reconsideration and withdrawal of the finding of lack of unity amongst Groups I-III and the requirement for restriction.

* * *

In light of the above remarks, reconsideration and withdrawal of the requirement for restriction made final in the Office Action, mailed April 15, 2008 respectfully are requested.

Respectfully submitted,


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